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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,394	07/29/2003	Kazuhiko Matsumura	2003_1003A	3969

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EXAMINER
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SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/628,394

Applicant(s)

MATSUMURA ET AL.

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on responses filed on 1/19, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/20/03, 12/17/03</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This application claims benefit of the foreign application:  
JAPAN 222149/2002 with a filing date 07/30/2002.
2. Claims 1-12 are pending in the application.

### ***Responses to Election/Restriction***

3. Applicant's election with traverse of Group I claims 1-12, in part, in the reply filed on January 19, 2005, is acknowledged. The traversal is on the grounds that the claimed processes of Groups I-III of the present application are recognized as preparing a single compound of formula (2). This is found persuasive, and the reasons are given, *infra*.

### ***Status of the Claims***

4. Claims 1-12 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-12, in part, drawn to a process of preparing compounds of formula (2), wherein the variables  $R^1$ ,  $R^2$ , and  $R^3$  independently do not represent heterocyclic group or heteroaryl, or the variable  $R^1$ ,  $R^2$ , and  $R^3$  independently are not substituted with heterocycle or heteroaryl; variables  $R^1$  and  $R^2$  together do not combine to form a heteroaryl or heterocyclic ring, variables  $R^2$  and  $R^3$  together do not combine to form a heteroaryl or heterocyclic ring.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups of formula (2) (i.e., heteroaryl or heterocycle of the variable  $R^1$ ,  $R^2$ , and  $R^3$ ) which differ from those of the elected invention, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 548 subclass 215(+) (oxazole), class 548 subclass 300.1(+) (diazole), class 546 subclass 249 (+) (pyridine), class 546 subclass 134(+) (quinoline), class 544 subclass 358(+) (piperazine), class 544 subclass 106(+) (morpholine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Since the newly added claims are commensurate with the scope of the invention, therefore, the invention claims, 1-12, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-12, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, a method for producing a compound of formula (2) using a starting material compounds of formula (1) without limitation of another starting material, i.e., hydrogen, acid, or catalyst, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, see claim 1, page 3, lines 2-3. Incorporation of the essential starting material hydrogen, acid, or catalyst would obviate the rejection, see page 7 of the specification.

6. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for making a compound of formula (2)

using starting materials compounds of (1), and hydrogen, catalyst, or acid, does not reasonably provide enablement for a process for making a compound of formula (2) using starting materials compounds of formula (1), and another starting material, i.e., copper chromite, see claim 1, page 3, lines 2-3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials.

2) State of the prior art.

The reference Seido et al. 5,859,249 does not indicate which compounds of instant processes may be useful in the claimed invention. Seido et al. '249 is pertaining to a novel 2-phenyl-2 (2'-piperidinylidene) acetate derivative and a process for manufacturing the same.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Applicants claim a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials. Applicant's specification does not enable the public to prepare such a numerous "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials", by the instant examples disclosed in the specification.

4) Level of predictability in the art.

Applicants claim a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials, remains highly unpredictable, see claim 1, page 3, lines 2-3. Different types of the genus of the processes "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials" in the specification, there would be little predictability in the scope of claimed compounds.

5) Amount of direction and guidance provided by the inventor.

Applicants claim a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting

materials, encompasses a vast number of processes. Applicant's limited guidance does not enable the public to disclose such a numerous amount of "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials" in the specification. There is no enablement for "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials", i.e., copper chromite, many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

Applicants claim a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials, encompasses a vast number of processes. Applicant's limited working examples do not enable the public to prepare such a numerous "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials". Applicants claim "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials", however, the specification provides only limited examples of processes.

7) Breadth of claims.

The claim is extremely broad due to the vast number of possible "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials".



8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain "a process for making a compound of formula (2) using starting materials compounds of formula (1) without limitation of another essential starting materials" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. Incorporation of limitation of claims 2-6, i.e., a metal complex of formula (7) or (8), into claim 1 would obviate the rejection, see page 7 of the specification.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, page 3, lines 2-3, recites the limitation "to an asymmetric hydrogenation", is ambiguous and indefinite. It is note that the term "to an asymmetric

hydrogenation" is drawn a named chemical reaction or process, it does not directly direct to the final product of formula (2). It is suggested that incorporation of the compound of formula (2) and another essential starting materials, i.e., acid, alcohol, or metal complex, into the claims, would obviate the rejection.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point

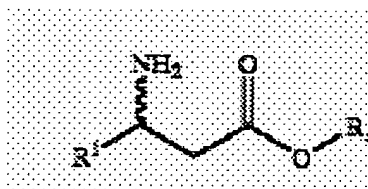
out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs's US 6,784,311 in view of Berlingozzi et al. publication, Gazzetta Chimica Italiana, 1954, 84:393-404, see CAS:49:27881. Fuchs's '311 is 102(e) reference.

Applicants claim a process of making a compound of formula (2) using starting material a compound of formula(1), the processes are found in the pages 5-53 of the specification.

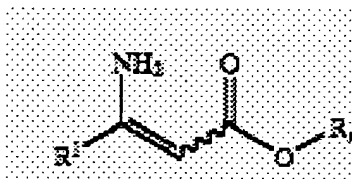
**Determination of the scope and content of the prior art (MPEP §2141.01)**

Fuchs discloses a process of making a compound of formula (I) or its salt,



, wherein R is alkyl and R<sup>1</sup> is hydrogen, alkyl, or phenyl,

comprising a step using a starting material a compound of formula (II),



, see columns 3-4. A number of examples have been

specifically exemplified, see Examples 1-3 on columns 2-3, i.e., methyl (RS)-3-aminobutyrate hydrochloride.

**Determination of the difference between the prior art and the claims (MPEP**

**§2141.02)**

The difference between instant claims and Fuchs's processes is that the instant variable  $R^2$  represents hydrogen or alkyl, while Fuchs's is hydrogen at the same position. Moreover, Fuchs silence the optically enantiomer of the compound of formula (I).

Berlingozzi et al. disclose a process of resolutions of the racemates of disclosed compounds (i.e., amino acid) by chromatography, see CAS: 49:27881.

**Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)**

One having ordinary skill in the art would find the instant claims 1-12 prima facie obvious **because** one would be motivated to employ the processes of Fuchs and Berlingozzi et al. teachings to obtain the instant processes for preparing an optically active compound of formula (2), wherein the variable  $R^1$  and  $R^2$  independently represent hydrogen, alkyl, or aryl, the variable  $R^3$  represents an alkoxy group, an aralkoxy group, aryloxy group, and a starting material of formula (1) is used, and optically active compounds of formula (2) are obtained by chromatography.

The motivation to make the claimed processes derives from the expectation that the instant claimed processes derived from known Fuchs processes and Berlingozzi et al. teachings would obtain same optically active products with similar yields to that which is claimed in the reference.

***Objection***

10. Claims 1-12 are objected to as containing non-elected subject matter heteroaryl or heterocyclic group, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*for* *Joseph K. McKane*

Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626

*R.S.*

Robert Shiao, Ph.D.  
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March 30, 2005